

December 19, 2003

Sarah Loftus McLallen
Manager, CHEMSTAR
The American Chemistry Council Petroleum Additive Panel
Health, Environmental, and Regulatory Task Group
1300 Wilson Boulevard
Arlington, VA 22209

Dear Ms. McLallen:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for 3-(Decyloxy)tetrahydrothiophene,1,1-dioxide posted on the ChemRTK HPV Challenge Program Web site on August 20, 2003. I commend The American Chemistry Council Petroleum Additive Panel Health, Environmental, and Regulatory Task Group for its commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that the Panel advise the Agency, within 60 days of this posting on the Web site, of any modifications to its submission. Please send any electronic revisions or comments to the following e-mail addresses: oppt.ncic@epa.gov and chem.rtk@epa.gov.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

-S-

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: W. Penberthy
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:
3-(Decyloxy)tetrahydrothiophene,1,1-dioxide**

Summary of EPA Comments

The sponsor, The Health, Environmental, and Regulatory Task Group (HERTG) of the American Chemistry Council Petroleum Additives Panel submitted a test plan and robust summaries to EPA for 3-(Decyloxy)tetrahydrothiophene, 1,1-dioxide (CAS No. 18760-44-6) dated August 11, 2003. EPA posted the submission on the ChemRTK HPV Challenge Web site on August 20, 2003.

EPA has reviewed this submission and has reached the following conclusions:

1. Physicochemical Properties and Environmental Fate. The submitter needs to provide measured melting point data. The submitter also needs to use a level III fugacity model.
2. Health Effects. Adequate data are available for acute toxicity and gene mutations for the purposes of the HPV Challenge Program. EPA agrees with the submitter's plan to conduct a combined repeated-dose/reproductive/developmental toxicity test and a chromosomal aberration study. The submitter needs to correct one robust summary.
3. Ecological Effects. EPA agrees with the submitter that testing is needed for fish and aquatic invertebrates.

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

**EPA Comments on the 3-(Decyloxy)tetrahydrothiophene, 1,1-dioxide
Challenge Submission**

Test Plan

Physicochemical Properties (melting point, boiling point, vapor pressure, water solubility, and partition coefficient)

The data submitted for water solubility are adequate for the purposes of the HPV Challenge Program. EPA agrees with the submitter's proposal to provide measured data for boiling point, vapor pressure, and octanol/water partition coefficient following OECD guidelines.

Melting point. In Table 1, the submitter indicates that a melting point is not applicable. EPA disagrees. The submitter needs to provide measured melting point data for this chemical. EPA located a measured melting point from Beilstein and another from STN file CA which are similar in value, 33.5-34°C and 34.5-35.5°C, respectively.

Environmental Fate (photodegradation, stability in water, biodegradation, fugacity)

The data submitted for biodegradation are adequate for the purposes of the HPV Challenge Program. EPA agrees with the submitter's test plan for photodegradation and hydrolysis.

Fugacity. The submitter proposes to evaluate fugacity using level I fugacity modeling. Although EPA had previously recommended the use of level I, this model is somewhat limited. EPA now recommends the use of the level III model, which provides a more rigorous level of analysis. EPA believes that values based on a level III fugacity model are more realistic and useful for estimating a chemical's fate in the

environment. The submitter should not use estimated physicochemical data as inputs when running the model. The use of estimated or calculated values introduces uncertainties that then become magnified in modeling applications.

Health Effects (acute toxicity, repeated-dose toxicity, genetic toxicity, and reproductive/developmental toxicity)

Adequate data are available for acute toxicity and gene mutations for the purposes of the HPV Challenge Program. EPA agrees with the submitter's plan to conduct a combined repeated-dose/reproductive/developmental toxicity screening test (OECD TG 422) and a chromosomal aberration study (OECD TG 473). The submitter needs to correct one robust summary.

Ecological Effects (fish, invertebrates, and algae)

The data submitted for green algae are adequate. However, the submitter needs to provide QSAR data to support this data because WAF concentrations were not measured. EPA agrees with the submitter that testing is needed for the fish and daphnia endpoints.

Specific Comments on the Robust Summaries

Health Effects

Acute toxicity. In the acute oral toxicity study summary the unit for the dose levels is written as "ml/kg," but the LD₅₀ is reported as "g/kg." Without knowing the chemical's density, it is incorrect to assume that 10 ml/kg is equivalent to 10 g/kg. The submitter needs to provide the corresponding values in "g/kg."

Followup Activity

EPA requests that the submitter advise the Agency within 60 days of any modifications to its submission.

References

Beilstein EV 17/3 p. 66: (Mu. et al.).

STN file CA: CA72:100397 (Bezmenova, T. E. and Dorofeeva, R. A., Khim. Str., Svoistva Reaktivnost Org. Soedin (1969), 73-75).